The Role of Regulation in Quality Improvement

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THE QUALITY OF HEALTH CARE IS NOT HEAVILY regulated. Except for clinical laboratories and nursing homes, few areas of health care are governed by rules, statutes, or laws. Instead, the industry has been allowed to self-regulate, which means that the rules regarding quality in health care are largely self-imposed. Perhaps in no other industry has the privilege of profession been so dominant.

Over the course of the last 25 years, the field of health services research has bloomed, as have new methods for measuring the quality of health care. Before 1970, quality existed simply in the eyes of the beholder. Since then, however, various tools have been devised to measure health status, satisfaction, and a series of outcomes.

For the past ten years, health care has struggled to integrate industrial methods of quality improvement. Known in health care as "continuous quality improvement," these industrial models emphasize self-motivation to improve in cycles. Only in the last five years have the two streams of health services research and continuous quality improvement come together (Brennan and Berwick 1996; Gosfield 1997).

Now that we are developing methods to assess quality and to integrate the newly emerging data into improvement of health care, we

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might expect regulation to become more effective. In order to judge whether regulation has evolved, it is critical to find the answers to three questions:

1. Is there measurable evidence that regulation is working to improve the quality of health care?
2. Are regulators aware of the tools developed by quality researchers, and are they integrating them into their oversight activities?

After answering these two questions, we can then address the final one:

3. Is there a way to combine continuous quality improvement and modern methods of quality measurement into a new regulatory format?

The task is both descriptive and synthetic. As we shall see, the description will suggest that there is little intertwining of quality improvement, quality measurement, and regulation. However, the prescription will indicate that this need not be the case and, in fact, that there have been some impulses in the right direction.

Space does not permit a complete review of all aspects of health care and its regulation. For this reason, I will leave aside certain issues: First, in my review of health care providers, I will omit the topic of long-term care and its regulation. Second, I cannot review all sources of regulation, particularly self-regulation that results from adherence to ethical criteria, a subject that has been addressed in some detail elsewhere (Veatch 1995). As managed care becomes more prominent, the role of ethics will become increasingly complicated (Rodwin 1995). Third, I will not address regulation that is designed to control costs. These issues aside, I turn to an analysis of regulation of quality.

The Theoretical Basis for Regulation in Health Care

Experts in regulation often avoid defining the term (Breyer 1982). I have referred elsewhere to regulation as any set of influences or rules

exterior to the practice or administration of medical care that imposes rules of behavior (Brennan and Berwick 1996, 4). I am particularly interested in rules developed by state legislators and public agencies and in common law rules developed by judicial precedent. To paraphrase another legal theorist, I will address rules that are prescriptive rather than descriptive (Schauer 1991).

Government regulation has a long history. In the 1930s, the New Deal gave tremendous impetus to federal oversight of the economy (Vietor 1994). Another burst of regulatory activity occurred when the redistribution impulses of the Great Society strengthened the earlier New Deal initiatives. Surprisingly, under Presidents Nixon and Ford a host of federal regulatory administrations was added to the bureaucracy in Washington, but the system began to unravel when President Clinton moved toward deregulation (Ayres and Braithwaite 1992).

As Breyer notes, a few common themes run through these regulations, which were designed to achieve certain ends: constrain decentralized, individual decision making in favor of a more coordinated, cohesive approach; control monopolies; provide consumer information; decrease moral hazard and limit insurance arrangements; and balance public welfare against private consumer choice. Regulators accomplish these goals primarily by setting standards through rule making and, secondarily, by using methods of culling.

The problem, to put it bluntly, is that regulation often leads to strife between regulators and the regulated industry, and thus to frustration of the regulatory intent. During the last few years, students of regulation have sought methods to decrease this friction. John Braithwaite, for example, has led the way in advocating a mix of persuasion and punishment to achieve regulatory goals. He would allow extensive use of self-regulation but would impose certain boundaries on industry license. Regulators would retain the ability to sanction the industry in order to ensure that self-regulation occurs, an arrangement he calls "enforced self-regulation." He has developed a full model, entitled "responsive regulation," in collaboration with Ian Ayres (Ayres and Braithwaite 1992).

Don Berwick and I have argued that responsive regulation entails at least five different approaches to improving quality (Brennan and Berwick 1996). The first is repair: identifying quality deficiencies and taking swift action to correct them. The second approach is culling, or removing defects from a system. We have suggested that culling, espe-

cially through licensing and disciplinary actions, is the most prevalent method of regulating quality in American health care. A third way is to encourage copying. Japanese industry, for example, provides forums as a way for manufacturers to learn about competitors' innovations. Elementary continuous quality improvement principles give rise to the fourth approach, which can be defined as learning through cycles. First described by Shewart (1937), the Plan-Do-Check-Act cycle summarizes the learning formats used by entities that are engaged in continuous improvement. Fifth, quality improvement emerges through creativity. Some organizations cultivate an atmosphere in which creativity thrives.

Quality-improving regulation in any industry should take advantage of one or more of these five methods to attain its goals. Unfortunately, regulation in every industry, particularly health care, often relies solely on culling. This tendency in turn retards development of other approaches, as culling is often converted to policing and quality improvement is treated as a matter of removing defects rather than as a continuous process of improving standards of health care or, in the case of other industries, manufacturing better products. Thus, traditional regulation can frustrate continuous quality improvement wherever it is applied.

As we shall see, regulatory formats are changing in health care. A few salutary developments indicate an awareness that traditional culling is corrosive. These developments point the way toward a better mix of continuous quality improvement regulation and modern methods of measurement.

Regulation of Health Care Providers

Physician Regulation

Physician regulation is perhaps the best example of a culling methodology. Physicians are regulated by state licensure boards, which require them to submit information periodically. They also solicit information from patients and other consumers about physicians' behavior. Many physician licensure boards also receive reports from credentialing committees at hospitals.

Licensure boards demonstrate how important self-regulation has been to medical care. As recently as the late 1960s, most licensure boards

were composed of individuals appointed or nominated by medical societies (Derbyshire 1969). Only slowly did judicial supervision[1] and legislative control transform licensure boards into public entities, but the shift has barely changed the efficacy of the oversight by medical licensure boards. From 1963 to 1967, fewer than 200 licenses were suspended across the United States (Derbyshire). Although today the number of disciplinary actions has increased to 3,000 each year (among nearly 600,000 medical doctors), fewer than 10 percent of these are for poor-quality care (Van Tuinen et al. 1995).

Boards can employ a variety of sanctions. They can write letters of admonition, engage in private censure, act in conjunction with quality assurance committees at hospitals, resort to public censure, and revoke licenses for definite or indefinite periods of time. Jurisdiction can range from a narrow definition, which might apply to impairment by drugs or alcohol, to a broader determination, which might cover lack of good moral character.[2]

The last decade has seen little improvement in the disciplining of physicians. Many tort reform measures enacted in the mid-1980s awarded new powers to boards of registration and other licensure boards. Unfortunately, legislatures often failed to provide them with the funds necessary to exert their new power.

As a result, the efficacy of licensure boards has been questioned. They have neither the funds nor the personnel to address major policy issues; instead, they are forced to emphasize mundane licensure activities (Andrew and Sauer 1996). Robert E. Porter, the past president of the Federation of Boards of Licensure, has suggested a need for radical change in the roles and functions of these boards (Porter 1995).

A review of the situation in light of the three questions I posed in my introduction uncovers no evidence that boards of registration affect quality of care. Although the ability to revoke the licenses of physicians who abuse drugs, have sex with their patients, or commit gross infractions is clearly helpful, I cannot cite any evidence that the general quality of medical care is improved by this method of removing a few bad apples. Nor is it clear that boards either are aware of quality measures or are integrating them into their responsibilities.

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[1] *Falcone v. Middlesex County Medical Society*, 170 A.2d 791 (N.J 1961) 800.

[2] *Raymond v. Board of Registration of Medicine*, 443 N.E.2D391 (Mass. 1982).

Hospitals

Many state departments of health license or certify hospitals. The majority of health departments rely on the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to certify their quality, as does the federal Medicare program. The JCAHO was formed in 1951, arising out of the Hospital Standardization Program of the American College of Surgeons. Commissioners are nominated by the major professional organizations, including the American Hospital Association, the American College of Physicians, and the American Medical Association. The JCAHO is an example of self-regulation, despite the presence of several public members on its board.

The JCAHO relies on triennial audits or surveys. Because the criteria or standards of care are constantly changing, the commission remains in contact with appropriate personnel at hospitals during the periods between surveys. Until very recently, the results of all audits were confidential. The traditional JCAHO audits relied on structural measures of quality. The commission expected to examine the minutes of important committee meetings, to review the records of specific measures, such as refrigerator temperatures, and to confirm the presence of safety measures, such as fire alarms. The surveyors closely scrutinized the credentialing committees' oversight of the quality of hospital medical staff.

Hospitals have traditionally done well in the surveys. Only 1 to 2 percent of hospitals that seek accreditation do not achieve full status (Roberts, Coale, and Redman 1987). This contrasts with the original Hospital Standardization Survey in 1917, which approved only 89 of 692 hospitals with more than 100 beds for full accreditation.

Federal regulators have endorsed the JCAHO accreditation as sufficiently rigorous to qualify for Medicare certification.[3] Most states also accept JCAHO accreditation for certification purposes. New York has long been an exception, but some of that state's hospitals have pushed for JCAHO accreditation to suffice, and the New York State Department of Health has signaled that it might be willing to agree to this idea (Hospital Association of New York 1993).

When we view JCAHO accreditation against my three initial questions, however, it is apparent that the JCAHO it is not associated with improving the quality of care (Burstin, Lipsitz, and Brennan 1992).

[3] 42 U.S.C.A. §1395X (e) and 1395 bb (1992).

Because the accreditation process is designed to reduce risk, proving effectiveness is inherently difficult. Yet, it is interesting that although information on JCAHO variances has been available to the public for some time, researchers have not attempted to correlate the data with other quality measures.

The JCAHO fortunately is aware of modern methods of measurement and improvement. Under Dr. Dennis O'Leary's leadership, the JCAHO has begun to reengineer its methods, and, in fact, its activities are an encouraging sign that continuous quality improvement will become a more important component of regulation in the future.

When he assumed his position in 1985, O'Leary and his team drew up their "Agenda for Change" to overhaul the JCAHO (O'Leary 1991). They began to replace its vague structural standards with guidelines that allowed hospitals to demonstrate how they were attempting to improve quality of care. The organization also required hospitals to show evidence that they were monitoring and evaluating these standards. In particular, the commission insisted that the evaluation of improvements should be based on reasonable measures of quality. The commission's intent was to persuade hospitals to reduce compartmentalization resulting from adherence to specific rules and instead to think in terms of organizational tasks (Brennan and Berwick 1996, 176).

The new JCAHO agenda also emphasized outcome measurement, which was inaugurated with the Indicator Measurement System (IMS). The IMS was created to show hospitals how they could calculate specific rates of indicators like cesarean section and central line infections. However, many hospitals were unable to follow through on this prescription.

Taking another tack, the Joint Commission recently announced the ORYX initiative, which allows hospitals to choose their own benchmark measures and emphasizes flexibility, institutional choice, and quality improvement. The JCAHO has also become more sensitive to the costs of outcome measurement, which became a major issue under the IMS.

During the last decade, the JCAHO standards have been completely redesigned. Although they still rely on the survey format, which can evoke the feel of an inspection, the surveyors and the organization are much more cognizant of continuous quality improvement, especially Plan-Do-Check-Act cycling, and of outcome measurement. Indeed, it would seem that the JCAHO is nearly ready to begin helping hospitals to engage in copying and creativity management, a topic I will discuss in the final section.

Perhaps the most important federal contribution to the improvement of hospital care is the Medicare program's Peer Review Organizations (PROs), which succeeded the Professional Standard Review Organizations (PSROs) . The PSROs were created by the Social Security Act Amendments of 1972 and were intended to constrain costs in the Medicare program through utilization review.[4]

The Reagan administration, acting on its commitment to market-based reform, began to replace the PSROs with the Peer Review Organizations, which are local organizations that provide utilization review for Medicare (Mellette 1986; Jost 1989). Over the past decade, the Health Care Financing Administration (HCFA) has added a quality oversight function. In its "Scopes of Work," the HCFA awards contracts with explicit requirements for promoting quality. The Health Care Quality Improvement Initiative, launched in 1992, endorsed the use of uniform outcome measures to assess quality of care. Since that time, HCFA has pushed the PROs to develop "partner" relationships with hospitals and has insisted that PROs focus on patterns of concern rather than on individual problem cases.

It remains unclear at this point whether the PROs have affected quality of care (Rubin et al. 1992), but the recent developments are salutary. HCFA has recognized that quality can be improved only through systematic efforts based on review of empirical data.

Health Maintenance Organizations

Today the other major providers of health care are the managed care organizations. Although one or another form of managed care organization has existed since the early part of the twentieth century, the Health Maintenance Organization Act of 1973 launched the modern industry.[5] The HMO Act mandated that employers offer HMO membership as an alternative to other health care plans; provided capital for development; and preempted state laws that banned corporate practice of medicine. After suffering through an industrywide solvency crisis in the mid-1980s, managed care organizations have now continued to grow, spurred by the lower premiums they can offer employers.

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[4] 42 U.S.C.A. 1301 (1972).

[5] 42 U.S.C.A. §300E(b) (1)A-V (1996).

Health maintenance organizations have traditionally been regulated as hybrid insurance companies. For example, HMOs in Maryland are required to have regular hours; to provide 24-hour access to physicians; to give each member an opportunity to select a primary care physician; and to offer both primary care and appropriate preventive services. Managed care organizations must have a written plan for implementing these standards, and they are required to install internal peer review systems.[6]

After the fiscal crisis of the mid-1980s, the states stipulated that managed care organizations must set aside significant reserves (Brennan and Berwick 1996, 157). This fiscal requirement, which has long been applied to insurance companies, has become part of state oversight in nearly every jurisdiction.

Several states have aggressively regulated the managed care organizations in their localities. For instance, the California Department of Corporations enforces the Knox–Keene Health Services Plan Act of 1975, which permits state authorities to conduct on-site surveys of plans and/or to levy fines against them. The JCAHO conducts the surveys under contract with the Department of Corporations.

The growth of managed care in the last three years has been accompanied by a tremendous increase in attention to oversight. Regulatory trends can now be recognized. The most controversial "new breed" of statutes has been created through legislation. Legislators, often influenced by providers, have decided that managed care constructed an overly parsimonious standard of care. The new statutes "re-set" the standard. Maternity length-of-stay bills may be the most publicized response to this viewpoint (Pallarito 1995).[7] To cite another example, the New Jersey legislature is considering mandating 48- to 72-hour hospital stays for lymph node–dissection and mastectomy patients, respectively (Bureau of National Affairs 1997).

On a slightly different track, "direct access" provisions are becoming more attractive to state legislatures. These laws permit health care plan members to bypass the primary care physician and go directly to a specialist without a referral from a "gatekeeper," who is usually a primary care provider. The specialties that would most often be subject to (or would benefit from) direct access provisions include obstetrics/

[6]Maryland Code Ann. §19-705.1 (1994).

[7]Newborns' and Mothers' Health Protection Act of 1996; 42 U.S.C.S. §30088-4 (1997).

gynecology care and emergency medicine (Bureau of National Affairs 1996a; Gardner 1996).

Although early legislation dealt with "selection" of physicians (any willing provider laws), more recent initiatives address the narrower issue of "deselection" and physician due process rights. Deselection of providers for reasons unrelated to competence has been prohibited by statute in Oregon, Texas, Maine, Rhode Island, Indiana, and New York (Bureau of National Affairs 1996b). These states require that a physician be notified of the reasons for deselection, and their laws also address the impact of deselection on continuity of care.

The movement to regulate managed care has led to serious efforts at the federal level. The President's Commission on the Quality of Care recommended a series of regulatory approaches.[8] Various bills are now making their way through Congress, with most attention focused on proposals by Senator Edward Kennedy of Massachusetts[9] and Representative Charles Norwood, Jr., of Georgia.[10] All the bills cover some of the regulatory methods I have discussed, with a few innovations that include preemption of the Employee Retirement Income Act (discussed below).

Much of the *sturm und drang* over managed care regulation overlooks the fact that for years managed care organizations have self-regulated in much the same way that hospitals have done through the JCAHO. The National Committee for Quality Assurance (NCQA) was founded in 1979 by the Group Health Association of America and the American Managed Care Review Association. Spurred by grants from nonprofit organizations like the Robert Wood Johnson Foundation, the NCQA began to conduct surveys similar to those of the JCAHO. (In fact, the JCAHO and the NCQA are competitors for accreditation of HMOs.) By now a mature overseer of managed care operations, the NCQA has devised accreditation standards for six areas: preventive health services, medical records, utilization management, medical rights and responsibilities, credentialing, and quality improvement. The NCQA accreditation process recognizes and encourages continuous quality improvement,

[8] Advisory Committee on Consumer Protection and Quality in Health Care, Consumer Bill of Rights and Responsibilities (1998).

[9] Patient Bill of Rights Act 51840, 105th Cong. 2nd Sess. (1998).

[10] Patient Access to Responsible Health Care Act, H.R. 1415 105th Cong. 1st Sess. (1997).

and its review process resembles that of the JCAHO: both organizations contribute written information and a survey team subsequently visits the sites.

The NCQA has also developed a set of performance measures, the Health Plan and Employer Data Set and Information Set (HEDIS), in response to the question asked by employers: "How do I understand the value of what my health dollars are purchasing?" (National Committee for Quality Assurance 1994). HEDIS comprises specific components: quality, access, and patient satisfaction; membership and utilization; and financial issues. Each area has detailed reporting requirements. The preventive medicine component, for instance, requires health plans to report rates of childhood immunization, cholesterol screening for particular populations, mammography screening for women over the age of 40, and Pap smear rates for women aged 15 to 70.

The critical role played by quality measures in NCQA accreditation is admirable. Although there has been little external validation of its accreditation process, the NCQA has moved more quickly than the JCAHO to public disclosure. Participating managed care organizations agreed to publish their scores on HEDIS criteria as part of the Report Card Pilot Project in 1993.

Unfortunately, regulation of managed care has not been evaluated with modern quality measurement tools. Indeed, it is not certain that regulation of managed care is oriented to problems with quality. The experience with 48-hour length of stay after a normal, spontaneous vaginal delivery is a case in point. Although many states, and now the federal government, have passed laws mandating length of stay (Annas 1995), it is not clear that these laws are addressing a significant quality problem. Recent evidence seems to suggest that reduced length of stay does not affect maternal or child health (Liu et al. 1997; Mandl et al. 1997). It may be that regulators of managed care rely too often on misleading anecdotes and not enough on real information about deficiencies that are a direct result of managed care controls. In fact, it has been suggested that regulation is undermining the important public health promotion that managed care organizations have carried out (Halverson et al. 1997).

In summary, the search for better regulation of managed care continues. This may be accomplished through broadening the scope and intention of NCQA accreditation (Prager 1997). Alternatively, it may involve more systematic regulation by states (Schlesinger 1997). Or it

may simply end in regulation of the amount of risk that managed-care organizations can assign to individual physicians (Swartz and Brennan 1996).

At present, however, we have no empirical evidence of efficacious managed care. Moreover, the recent, highly publicized efforts to "regulate managed care" show little regard for quality measure or improvement techniques. In contrast, NCQA accreditation has been admirably oriented to measurable processes and outcomes.

Other Sources of Quality Regulation

Tort Law

Many do not consider tort law when addressing regulation of health care quality, despite the fact that this branch of law has as one of its major social goals (in addition to compensation for injuries and corrective justice) the deterrence of behavior that leads to medical injuries. One quality outcome, for example, that is targeted by tort law is a negligent adverse event, defined as a medical injury caused by the failure of the practitioner to achieve the standard expected of a reasonable clinician. Tort law sanctions might also encourage improvements in patient satisfaction and other outcomes.

Malpractice law has evolved considerably over the course of the last 30 years (Weiler et al. 1993). Judges began to make changes in the common law during the 1930s and through the 1950s that eased liability standards for plaintiffs by changing certain doctrines. The opportunities for successful suits by plaintiffs were increased by relaxing the locality rule, integrating the doctrine of *res ipsa locquitur*, phasing out charitable immunity, and making various changes to informed consent law.

These changes did not induce an increase in medical malpractice litigation until the late 1960s, when the number of annual suits against physicians increased dramatically. The startling increases in rates of claims in the mid-1970s and mid-1980s drove physicians and insurers to complain to state legislatures of a medical malpractice crisis. The legislatures responded by enacting so-called tort reform: changes in the law designed either to make it more difficult for patients to file lawsuits or to decrease the value of the suit for the plaintiff, thereby reducing the contingency fees paid to plaintiffs' attorneys. Among the reforms were

caps on noneconomic damages, caps on economic damages, changes in statutes of limitation, and mandatory offsets of remuneration from other insurance sources. Eventually, reform resulted in the relatively stable situation that exists in the mid-1990s: claims rates are essentially unchanged while the severity (dollars per individual settled claim) continues to increase.

Malpractice litigation is an effective way to regulate providers because it is not subject to regulatory capture. The plaintiff's attorney is not hampered by self-regulation impulses or by state medical society lobbying efforts. Nonetheless, there is no reliable evidence that malpractice litigation improves health care quality.

In our studies of medical malpractice litigation, we have attempted to document the deterrent effect of malpractice. Regression analyses conducted in New York in 1984 suggested that areas with higher tort claims had lower rates of adverse events. Because it is not plausible that a higher quality of care would stimulate more litigation, it is more reasonable to assume that the tort activity had a positive impact. Perhaps even more interesting was the appearance of a deterrent effect in analyses of hospitals but not of individual physicians, which suggests that hospitals recognized the deterrence signal but that physicians did not. This comported with my view that individual physicians are unable to develop the necessary safety measures to protect themselves from tort claims, whereas hospitals are able to do so (Burstin, Lipsitz, and Brennan 1997).

I would add one more point about medical malpractice litigation as a regulator of quality improvement. Through the mid-1980s, malpractice claims were not coordinated as a quality signal; that is, news of claims brought in one state was not communicated to other states. The passage of the Health Care Quality Improvement Act in 1986, and the establishment of the National Practitioner Data Bank, cured this problem.[11] The Health Care Quality Improvement Act required that all disciplinary actions and paid malpractice claims against physicians be reported to a single federal data bank, assuring that physicians cannot simply cross state lines in order to escape the deterrent effect of disciplinary board sanctions or successful plaintiffs' actions. Hospitals must query the National Practitioner Data Bank before granting privileges to any individual physician.

[11] Health Care Quality Improvement Act of 1986, 42 U.S.C. §1101 et seq.

Today the most interesting developments in medical malpractice are the changes occurring in liability for managed care organizations. Long shielded from litigation by state laws declaring that managed care organizations were not health care providers, and by the failure of certain doctrines, such as vicarious and enterprise liability, to reach them, managed care organizations now face an uncertain liability future.

The changes in judicial interpretation of the Employer Retirement Income Security Act (ERISA) have had a significant impact.[12] ERISA is now being discussed widely in the medical literature, but only five years ago it was a poorly understood employee benefits issue (Mariner 1996). An influential footnote in a 1985 Supreme Court decision[13] clarified the point that ERISA preempted any state law relating to employee welfare benefit plans, including health plans. This, in turn, meant that state efforts to regulate health insurance plans, including managed care organizations, could be preempted by federal law. A state wishing to undertake a legislative initiative to promote quality in managed care organizations might find that the law was preempted by the federal statute, at least with regard to self-insured plans. ERISA was also interpreted as preempting state tort law.

This situation has begun to change as state and federal courts search for ways to overcome ERISA preemption. For example, the Connecticut Supreme Court has recently held that a lawsuit brought by physicians and their patients in response to a physician's unilateral termination from his preferred provider network was not preempted by ERISA. In *Napoletano v. Cigna*,[14] the court held that the plaintiff's claim was valid under the state unfair trade practices and unfair insurance practices act. As such, the suit did not "relate to" an employee benefit plan, which is the touchstone of ERISA preemption.

Similar developments have occurred in the context of negligent oversight of utilization review. The initial federal cases had suggested that negligent utilization review could not be addressed by state negligence law owing to the preemptive effect of ERISA.[15] Now this view has

[12] 29 U.S.C. §1144 (b) (2) (a) (1996).

[13] *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724 (1985).

[14] 680 A.2d 127 (Conn. 1996); cert. denied 117 S.Ct. 1106 (1996).

[15] *Corcoran v. United Health Care, Inc.*, 965 F.2d 1321 (5th Cir. 1992), cert. denied, 113 S.Ct. 812 (1992).

begun to change. Consider the case of *Pappas v. Asbel*,[16] which follows *Dukes v. U.S. Healthcare, Inc.*[17] The plaintiff alleged that a cost-containment protocol prevented her timely transfer to a facility where she could have received up-to-date, appropriate neurological care. The court found that the negligent delay was occasioned by a cost-containment protocol set by a for-profit organization and was not consistent with—in fact, was diametrically opposed to—the original focus of ERISA, which is the protection of workers' rights. The court concluded that Congress could not have intended to foreclose recovery to plan beneficiaries who were injured by negligent medical decisions based on cost-containment rationale.

States have become aware of the potentially chilling effect of ERISA on malpractice suits against managed care organizations. Indeed, Texas has recently passed a law that makes managed care organizations liable for negligent utilization oversight. It was immediately challenged by insurers on ERISA grounds (*Modern Healthcare* 1997). Most federal proposals on regulation of managed care encourage and/or allow common lawsuits by explicitly overriding ERISA.

Yet, to this point, we lack empirical information on how tort litigation has affected quality improvement generally, and managed care particularly. Despite its admirable ability to elude regulatory capture, litigation of malpractice claims has not yet clearly demonstrated that it can improve the quality of medical care (Brennan, Sox, and Burstin 1996). Nor does it appear to be inducing defenders to employ continuous quality management methods or, better yet, to upgrade the quality of the care they offer, making it difficult to endorse malpractice litigation as a means to achieving a better quality of medical care (Leape et al. 1993).

Public Data Initiatives

The newest form of regulation for quality improvement is based on outcomes measurement. In over 40 states, government agencies, hospital associations, or volunteer organizations are devising methods to measure outcomes and compare hospitals.

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[16] 675 A.2d 711 (Pa. Super. 1996); petition for allowance of appeal granted, 686 A.2d 1312 (Pa. 1996).

[17] 57 F.3d 250 (3d Cir. 1995).

Outcomes measurement has been slow to arrive. The first steps were taken by HCFA in 1986, when it decided to publish standardized mortality rates for hospitals (Brennan and Berwick 1996, 200). Problems arose, first with severity adjustment and eventually with marginalization of the data by health care leaders, and HCFA ceased publication of these rates in 1993 (Berwick and Walt 1990). However, New York State persevered, first under the aegis of State Health Commissioner David Axelrod and then under that of his successor, Mark Chassin, in producing risk-adjusted mortality rates related to heart surgery (Hannan et al. 1994). Eventually, the New York data that ranked mortality rates by hospital were disclosed publicly.[18] Pennsylvania has followed a similar course, but its health department chose to rely on the MEDIS Group's severity-of-illness systems to standardize for mortality rates.

There are signs that the cardiac surgeon reporting system in New York has been ameliorating the quality of care (Hannan et al. 1994). Mortality rates appear to be decreasing, although some remain skeptical (Jenck 1997). The downward trend may be attributable to physician referral of high-risk patients out of state, but it seems more likely to be the result of hospitals' exercising greater care and being more selective in hiring their cardiac surgeons. On the other hand, Epstein's evaluation of the Pennsylvania reporting system leads to the conclusion that the data are having little effect either on cardiologists or on consumers and payors (Schneider and Epstein 1996).

No matter what the effect of these cardiac mortality rate systems in Pennsylvania and New York, it is clear that many other states are gearing up to track outcome measures. To give just one example, the Massachusetts Hospital Association has selected patient satisfaction with care as the benchmark for three diagnoses. This information was privately held for the first year but was made public in 1998. All hospital participation is voluntary, but the wide participation (80 percent of hospitals) indicates the interest of the provider community in this sort of initiative. Many other states are now engaged in a mix of measures, ranging from satisfaction to health status to mortality rates.

Perhaps the most vibrant of these efforts have been organized by employers. For instance, the Buyers Health Care Action Group in Minnesota plans to evaluate statewide data when it makes decisions about

[18] *Newsday Corp. v. New York State Department of Health*, 19 *Media Law Report* (BNA) 1477 (Sup. Ct. Albany County 1991).

where to send patients for procedures like coronary artery bypass grafting and hip replacement. The Cleveland Health Quality Choice Program provides a full report on quality and utilization in the hospitals in the Cleveland metropolitan area. The Federal Employees Benefits Program now releases report cards on various hospitals and managed care organizations.

These initiatives can be characterized as another example of culling bad apples. Alternatively, they may provide an opportunity to establish internal benchmarks and to compare the quality of hospitals and integrated delivery systems. One can also speculate on ways that these data could be used as the basis for continuous improvement. How the information is used by its collectors, especially state governments, will be critical. No one has shown that public initiatives are improving care, but at least they demonstrate a familiarity with empirical quality measures and are a positive step in the direction of improved health care delivery.

Partial Answers to Three Questions

Returning now to the three questions posed initially, we ask first, "Is there evidence that quality regulation is improving health care delivery?" This review has produced little evidence that regulation has improved the quality of health care. I have noted that empirical strategies could be used to evaluate new quality rules, but there are few standard approaches to quality regulation and few simple outcome measures to evaluate its efficacy. Although measures like mortality rates, readmission, or even patient satisfaction conceivably could be used to compare approaches, research on this possibility has not been done. As a result, we regulate in an empirical void, often addressing anecdotes and hysteria with far-reaching initiatives. The current efforts to regulate managed care are an excellent example of a poorly informed regulatory response.

Second, are regulators cognizant of quality measurement? The answer to this is fortunately "yes." The state data initiatives, the Joint Commission on Accreditation of Healthcare Organization's ORYX program, and the Peer Review Organizations' efforts to redesign the Scope of Work all suggest that quality measurement can be integrated into reg-

ulation. Of course, regulators are concerned about the state of quality measurement:

> There is much interest, for instance, in evaluating performance of the individual practitioner. On this front I am skeptical and suggest that we first learn how to crawl. We presently have the about same level of sophistication for measuring health-plan performance. On the bright side, we are rapidly learning about the use of measurement in organized delivery systems such as hospitals. (O'Leary 1995)

The ORYX endorsement of institutional leeway in choice of quality measures and the HEDIS reliance on specific criteria suggest that quality measures will be used more commonly in the future (Radical Statistics Health Group 1995).

Although these are encouraging developments, there is a significant gap between health services research and quality oversight. Consider the relation between quality outcomes and volume of services. Many studies have demonstrated that mortality following coronary artery bypass graft surgery may be related to the volume of procedures performed at specific centers (Grumbach et al. 1995). Mark Chassin has suggested a regulatory strategy that would centralize procedures at high-volume centers or that at least would monitor the number of procedures performed by individual operators.

Like many other hospitals, Brigham and Women's Hospital in Boston has begun to track the outcomes of procedures it carries out. The hospital is also examining the outcomes of individual operators and is recording both the total number of procedures and the outcomes in credentialing files.

To discover whether other institutions were following the same procedures, I conducted a survey of over 100 hospitals, which produced these initial findings: less than 10 percent recorded the number of cases performed in credentialing files; less than 5 percent were recording outcome measures. Thus, although research clearly shows that doctors should perform a threshold number of procedures to maintain proficiency, this finding apparently has not been transmitted to hospital credentialing committees. Nor has any state legislature or hospital association suggested that an individual should reach a threshold of experience before continuing to perform a procedure. Indeed, any such proposals would probably be the subject of significant legal challenges

(Brennan and Berwick 1996). The JCAHO stipulates that empirical information should be entered in credentialing files, but there is no information on hospitals' compliance with this requirement. In summary, despite initial steps to integrate quality measurement and improvement into regulatory oversight, there is considerable room for improvement.

Finally, we ask, can regulation promote quality measurement and continuous quality improvement? Astute observers, like Alain Enthoven, worry aloud that any form of regulation would stunt creativity and force slavish compliance with meaningless outcome measurement strategies (Enthoven and Vorhaus 1997). Moreover, any external oversight is prone to mindless policing: the regulator in effect becomes a line boss, investigating the work of physicians or hospitals in order to sanction poor performance. This inspection format, as Don Berwick has argued, frustrates efforts to initiate continuous quality improvement.

However, Berwick and I have argued that this need not be the case. The responsive regulation philosophy, as outlined by Ayres and Braithwaite, encourages self-regulation and innovation, provided that the regulatory agency is able to punish those who do not participate in reasonable programs. The PROs, under the fifth Scope of Work, the Joint Commission, and the NCQA are engaging in just this kind of responsive regulation by allowing organizations to set their own quality agendas, as long as these include measurement of outcomes and reasonable improvement efforts.

I have suggested some ways to reinforce this impulse. First, I recommend that regulators reduce the costs of inspection. The JCAHO and HEDIS surveys require time and attention that are taken away from the energy required for true quality improvement. As the NCQA and the JCAHO continue to minimize the preparation of materials needed for evaluation and to tailor their surveys to fit the internal needs and constraints of the institutions, the survey itself takes on the aspect of a quality consultation.

Second, I believe that regulation should be linked explicitly with shared aims. Regulators should define specific goals and then give hospitals or physicians the opportunity to meet them. We also recommend reducing the competition and duplication among regulators. Very soon, both the NCQA and the JCAHO will be interested in accrediting integrated delivery systems. Competition among accreditors and regulators could improve the accreditation process, but it might also lead to multiple (unnecessary) accreditation surveys.

We also recommend that regulators consider "safe havens" for major innovation. The JCAHO encourages organizations to explore new strategies to improve quality. Regulation can inhibit this kind of creativity. Re-engineering of delivery systems is stymied when regulators dictate the details of their structure.

All these suggestions can be subsumed within one primary goal: to build on existing efforts to integrate continuous quality strategies and quality measurement into regulation. The achievements of the regulators that are accomplishing this goal should be emulated and expanded.

Finally, we must engender public knowledge of quality measurement. Whether they come through voluntary efforts of providers, or are required by the state, any efforts to develop regionally standardized outcome measures and to provide this information to the public must be encouraged. Although some would argue that this is better done under the auspices of voluntary agencies than by state regulators (Wilensky 1997), there is no empirical basis to believe that state initiatives will fail (Derman 1997).

Slavish adherence to traditional principles of regulation, which are devoted to the task of culling "bad apples," will do little to improve the quality of medical care. Regulators, particularly the JCAHO and the NCQA, have realized this. Private and state institutions should be encouraged to continue to identify methods of regulation that permit organizations to measure their own quality, to gauge it against the standards of others, and to adopt strategies for change.

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